

<b>LIST OF REFERENCES CITED BY APPLICANT</b> (Use several sheets if necessary)	<b>ATTY. DOCKET NO.</b> 11808-045-999 (CAM: 120024-999045)	<b>APPLICATION NO.</b> 10/563,418
	<b>APPLICANT</b> Jungles <i>et al.</i>	
	<b>FILING DATE</b> July 24, 2007	<b>ART UNIT</b> 1614

### U.S. PATENT DOCUMENTS

<b>*Examiner Initials</b>	<b>Document Number</b>	<b>Date mm-dd-yyyy</b>	<b>Name of Patentee or Applicant of Cited Document</b>	
A01	4,778,794	10-18-1988	Naruse <i>et al.</i>	
A02	5,753,656	05-19-1998	Sakai <i>et al.</i>	
A03	6,288,067	09-11-2001	Okamura <i>et al.</i>	
A04	6,410,535	06-25-2002	Kashiwagi <i>et al.</i>	
A05	6,417,205	07-09-2002	Cooke <i>et al.</i>	
A06	2004/0058896	03-25-2004	Dietrich <i>et al.</i>	
A07	2006/0035900	02-16-2006	Moser <i>et al.</i>	
A08	2006/0040946	02-23-2006	Oppenheimer <i>et al.</i>	
A09	2008/0207624	08-26-2008	Sugita <i>et al.</i>	

### FOREIGN PATENT DOCUMENTS

<b>*Examiner Initials</b>	<b>Foreign Patent Document Country Code, Number, Kind Code (if known)</b>	<b>Date mm-dd-yyyy</b>	<b>Name of Patentee or Applicant of Cited Document</b>		<b>T</b>
B01	EP 1757293	02-28-2007	Daiichi Asubio Pharma Co. Ltd.		
B02	WO 2005/107759	11-17-2005	Daiichi Asubio Pharma Co. Ltd.		
B03	WO 2006/063215	06-15-2006	BioMarin Pharmaceutical Inc.		
B04	WO 2007/067570	06-14-2007	BioMarin Pharmaceutical Inc.		

### NON PATENT LITERATURE DOCUMENTS

<b>*Examiner Initials</b>	<b>Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.</b>	<b>T</b>
C01	FDA Center for Drug Evaluation and Research (CDER) Draft Guidance for Industry ANDAs: Pharmaceutical Solid Polymorphism Chemistry, Manufacturing, and Controls Information; December 2004	
C02	“Tetrahydrobiopterin tablets” by Schircks Laboratories, August 15, 2003.	
C03	“Data Sheet – Tetrahydrobiopterin” by Schircks Laboratories, September 16, 2003	
C04	“Summary of product characteristics-Tetrahydrobiopterin 10 mg/50 mg Tablets” by Schircks Laboratories, January 7, 2004.	
C05	“Certificate of Analysis” by Schircks Laboratories, March 11, 2005	
C06	“Tetrahydrobiopterin tablets” by Schircks Laboratories, January 8, 2008.	
C07	“Statement for the Record” from the file history of USSN 10/990,316, February 25, 2008	
C08	“Summary of product characteristics-Tetrahydrobiopterin tablets” by Schircks Laboratories, March 31, 2008.	

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<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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C09	Office Action mailed 08/06/08, U.S. Application No. 12/106,621	
C10	Office Action mailed 10/20/08, U.S. Application No. 12/106,621	
C11	Interview Summary mailed 10/31/08, U.S. Application No. 12/106,621	
C12	Notice of Allowance mailed 6/05/09, U.S. Application No. 12/106,621	

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